(19) FEDERAL REPUBLIC OF GERMANY
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GERMAN
PATENT OFFICE

(12) **Published Application**
(10) **DE 197 12 708 A 1**

(21) File number: 197 12 708.8
(22) Application date: 3/26/97
(43) Publication date: 10/1/98

[barcode]
(51) Int. Cl.[6]:
C 08 L 5/00
C 08 J 5/04
C 08 J 3/28
B 29 B 9/00
A 61 K 7/00
A 61 K 47/36
C 12 N 5/00
C 12 N 11/10
A 61 L 27/00
A 61 L 29/00
F 26 B 3/347

// C08L 5/08, 1/08, 3/04, 3/08, C08K 3/20, C08J 9/00

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(56)Citations:
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US 50 17 229
EP 07 27 232
EP 06 48 480
WO 95 18 635
J. Am. Chem. 1994, 116, pp. 7515–7522;
Derwent-Abstr. 93-088570/11;
Derwent-Abstr. 91-321580/44;
Caplus-Abstr. 1994: 703842

The following statements have been taken from the application filed by the applicant.

A request for examination has been made pursuant to § 44 Patent Code.

(54) Dried low-contaminant hydrocolloids and hydrogels

(57) Dried low-contaminant hydrocolloids and hydrogels comprise polysaccharides and possibly additives, which have been dried to a residual water content of 1 to 80 mass-% under the effect of the thermal energy of microwaves.
The dried low-contaminant hydrocolloids and/or hydrogels are used in pharmacology, cosmetics, medical technology, and biotechnology.

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Description

The present invention relates to dried low-contaminant hydrocolloids and/or hydrogels based on polysaccharides for use in pharmacology, cosmetics, medical technology, and biotechnology.

Soluble colloids in the form of hydrocolloids and insoluble colloids in the form of hydrogels based on polysaccharides are known.

The drying of the hydrocolloids or hydrogels required for the specific use may result in an undesired drop of the molar mass and in undesired chemical changes in relation to the starting product.

Known drying methods for polysaccharides are thermal drying by heat convection and freeze drying in vacuum.

WO 95 25751 describes the production of planar formations made of the polysaccharide hyaluronic acid by hot-air drying. The production of freeze-dried biomatrices on the basis of natural and modified polysaccharides is the subject matter of DE 43 28 329. These biomatrices have a cavity structure, into which liquids may penetrate rapidly and unobstructed. The freeze drying during the production of collagen sponges is described in DE 27 34 503, DE 29 43 250, and DE 40 28 622. The drying method also provides a spongy structure of the biomatrix here. The production of planar formations having a porous structure on the basis of hyaluronic acid and hyaluronic acid derivatives by freeze drying is the subject matter of DE 40 24 180.

The disadvantages of thermal drying of polysaccharides by heat convection are the inhomogeneous drying sequence and the thermal damage to the polysaccharides due to molar mass degradation and chemical changes. During short drying times, local overheating results, because the product dries first on the surface. The resulting external hard dried crust makes the further drying procedure in the interior of the material more difficult, chemical damage occurs due to molar mass degradation and chemical changes such as decarboxylation, and inhomogeneous products result in regard to the moisture content. Longer drying times at lower temperatures provide more uniform products in regard to the moisture content, but typically result in significant molar mass degradation in heat-labile polysaccharides, connected with oxidative changes and a drop of the material properties, in particular the elastic properties. A further result of long drying times may be microbial contamination of the polysaccharides and the degradation by microorganisms connected thereto.

The disadvantages of freeze drying of polysaccharides comprise the spongy structure of the freeze-dried products. Liquids may penetrate rapidly and unobstructed into the cavities of the freeze-dried polysaccharides and thus cause spontaneous disintegration of the network of the matrix. The property of water and active ingredient storage of the matrix is rapidly canceled out by this instant effect.

Compact surface layers having good material properties and long-term stability are required for coatings, spongy structures are unsuitable for this field of use.

The object of the present invention is therefore dried hydrocolloids and/or hydrogels based on polysaccharides, which are distinguished by high product homogeneity, are low in contaminants, and only have a small drop of the molar mass in relation to the starting products and are at most slightly chemically changed.

The object according to the present invention has been achieved by dried low-contaminant hydrocolloids and/or hydrogels, possibly in the form of planar formations, having a density of 0.05 to 1.50 g/cm³ and a residual water content of 1 to 80 mass-% on the basis of unmodified and/or modified natural, biotechnologically produced, and/or semisynthetic polysaccharides and possibly 0.01 to 60 mass-%, in relation to the hydrocolloids and/or hydrogels, of additives, the drying of the hydrocolloids and/or hydrogels being performed uniformly and carefully under the effect of the thermal energy of microwaves and possibly the thermal energy of heated gases and/or IR radiators while largely maintaining the starting molar mass.

The dried low-contaminant hydrocolloids and/or hydrogels have germination counts of at most 100 germs/g of dried hydrocolloid or hydrogel as a result of the microwave treatment.

The unmodified and/or modified natural, biotechnologically produced, and/or semisynthetic polysaccharides are preferably unmodified and/or modified pectins, chitins, chondroitins, heparins, starches, dextrans, pullulans, xanthans, welans, rhamsans, curdlans, alginates, carrageenans, keratans, hyaluronic acids, dermatans, gellans, schizophyllans, and/or polysaccharides made of carob flour, agar, gum Arabic, tragacanth gum, guar gum, fenugreek gum, locust bean gum, and/or tara gum.

Examples of modified polysaccharides are carboxy methyl starch, hydroxyethyl starch, dialdehyde starch, pectin ester, chitosans, etherified guar gum, acetylated hyaluronic acids, hyaluronic acids, and cross-linked or partially cross-linked hyaluronic acids.

The possibly contained additives are preferably 0.1 mass-% to 25 mass-% film-forming binders and/or thickeners, 0.01 mass-% to 0.25 mass-% preservatives, 1 mass-% to 30 mass-% stability-improving fibrous carrier materials and/or stability-improving carrier materials in the form of textiles and/or latticed planar formations, 0.05 to 10 mass-% mineral materials, 0.05 to 3 mass-% micelle-forming materials, 1 to 25 mass-% softeners, 0.05 to 30 mass-% cosmetic and/or pharmaceutical active ingredients, 1 to 30 mass-% vehicles for active ingredients, 0.05 to 2 mass-% antioxidants, 0.05 to 2% odorants, and/or 0.05 to 5 mass-% colorants, the proportions each relating to the hydrocolloids and/or hydrogels.

The film-forming binders and/or thickeners comprise plastics and/or semisynthetic modified natural materials, preferably starch ethers, sodium alginate, cellulose derivatives such as carboxy methyl cellulose, cellulose ether, cellulose esters and alkyl celluloses, polyvinyl acetate, polyvinyl alcohol, partially-saponified polyacrylic acid ester and/or partially-saponified polymethacrylic acid esters. An especially preferred film-forming binder and/or thickener is carboxymethyl cellulose because of the reversible water solubility and good compatibility, in particular for medical and cosmetic applications.

Examples of suitable preservatives are p-hydroxybenzoic acid, benzyl alcohol, and propylene glycol. For medical and cosmetic applications, in which skin irritations must be precluded, p-hydroxy benzoic acid ester and sorbic acid are especially suitable.

The stability-improving fibrous carrier materials and/or stability-improving carrier materials in the form of textiles and/or latticed planar formations preferably comprise cellulose, cellulose esters, calcium alginate, wool, cotton, silk, polyamides, polyesters, polyethers, polyvinyl alcohol, and/or polyolefins. These carrier materials increase the mechanical dry stability of the dried hydrocolloids and hydrogels, the form of the carrier materials is selected as a function of the application, e.g., sewing thread nonwoven formations based on cotton are suitable carrier materials for hydrocolloids having active ingredient properties in wound care.

Suitable mineral materials as additives in dried hydrocolloids and hydrogels are aluminum hydroxide, magnesium hydroxide, zinc oxide, calcium carbonate, talcum, bentonite, silicon dioxide, and/or wollastonite. These mineral materials stabilize the hydrocolloid or the hydrogel and/or regulate the electrolyte balance at the corresponding application point for medical applications.

Examples of micelle-forming materials are higher alcohols such as cetyl alcohol, stearyl alcohol, and wool wax alcohol, sodium lauryl ether sulfate, fatty acid amides, sodium salts of fatty acids, and lecithin. Nonionic emulsifiers like polyglycol esters and polyglycol ethers are preferred as micelle-forming materials.

Suitable softeners as additives for increasing flexibility in dried hydrocolloids and hydrogels are glycerin, glycerin alkyl ether acetate, polyethylene glycol diethyl hexoate, 2-ethylhexyl-p-hydroxybenzoate, stearyl citrate, and polyvinyl methyl ether. Glycerin is preferably suitable for medical and cosmetic applications.

Examples of cosmetic and pharmaceutical active ingredients are ethereal oils, corticosteroids, Pyribenzamine, pilocarpine nitrate, tyrothricin, folic acid, nicotinic acid amide, nicotinic acid ester. Vitamins such as vitamin A, vitamin B1, vitamin B6, vitamin E and agents which encourage skin penetration, like polyoxymethylene nonylphenol, are preferably used.

Liposomes are suitable as a vehicle for transporting active ingredients which contain the dried hydrocolloids and/or hydrogels as additives.

Examples of suitable antioxidants are thiodipropionic acid, tocopherol, and α-ionon. Ascorbic acid is preferably suitable.

The odorants may comprise natural odorant complexes, in particular ethereal oils, as well as synthetic uniform odorants such as limonene, phellandrene, cinnamyl alcohol, fenchyl alchohol, or geraniol. Odorants based on ethereal oils are preferred.

Natural vegetable colorants such as alkanna, calendula, crocus, indicum, carotene, lactoflavin, chlorophyll, and Santalum rubrum, color pigments such as barium sulfate, zinc oxide, titanium dioxide, and iron oxide, as well as synthetic colorants, e.g., based on triphenyl methane or anthraquinone, are suitable as additives for marking and/or pigmenting colorants contained in the dried hydrocolloids and/or hydrogels.

The hydrocolloids dried under the effect of the thermal energy of microwaves and possibly the thermal energy of heated gases and/or IR radiators preferably have a molar mass numeric mean of at least 75% of the molar mass numeric mean of the hydrocolloids used as the starting product. The molar mass numeric mean of hydrocolloids may be ascertained by GPC analysis in connection with light scattering measurements [Orvisky, E., Chromatographia (1994), 39 (5/6), 366–368; Vercruysse, K, J. Chromatogr., Pt. B Biomed.Appl. (1994), 656 (1), 179–190].

According to the present invention, the low-contaminant hydrocolloids and/or hydrogels which are dried uniformly and carefully while largely maintaining the starting molar mass are produced, possibly in the form of planar formations, having densities in the range from 0.05 to 1.50 g/cm³ and a residual water content of 1 to 80 mass-% on the basis of unmodified and/or modified natural, biotechnologically produced, and/or semisynthetic polysaccharides and possibly 0.01 to 60 mass-%, in relation to the hydrocolloids and/or hydrogels, of additives, as well as possibly 0.1 to 10 mass-%, in relation to the hydrocolloids and/or hydrogels, of propellants, according to a drying method under the effect of the thermal energy of microwaves and possibly the thermal energy of heated gases and/or IR radiators.

In the event of the possible additional effect of the thermal energy of heated gases and/or IR radiators during the drying of hydrocolloids and/or hydrogels, the effect of the thermal energy of the microwaves occurs simultaneously and/or after the effect of the thermal energy of heated gases and/or IR radiators. The ratio of microwave energy to the temperature and to the throughput quantity of the gas is selected in such a way that the proportion of the microwave energy to the total energy applied for drying the hydrocolloids is 95 to 10%. The gases used for drying the hydrocolloids are preferably entirely or partially

heated in the heat exchanger of the microwave generators.

It is advantageous that dried hydrocolloids and/or hydrogels in foamed form may also be produced by the method according to the present invention. Examples of propellants which the hydrocolloids and/or hydrogels may contain during the drying, possibly for defined setting of the porosity and density during the production of foamed, dried materials, are gas-cleaving propellants such as azodicarbonamide or cyanuric acid trihydrazide, high-volatility hydrocarbons and halogenated hydrocarbons such as pentane, isobutane, monofluorotrichloromethane, or difluoromonochloromethane, or gases such as nitrogen, argon, or carbon dioxide. Dried foamed hydrocolloids and/or hydrogels having densities in the range from 0.50 to 1.50 g/cm³ generally do not require any additional use of propellants, because the density of the closed-cell foamed material or the porosity of the open-cell foamed material may be controlled by the energy introduction of the microwave treatment and the diffusing kinetics of the water vapor resulting therefrom. The foam density and/or the porosity of the dried material determine the swelling and/or absorption speed during application.

The introduction of the thermal energy of microwaves of a frequency of preferably 2.4 to 2.5GHz is performed according to the present invention as continuous power or as modulated and/or pulsed power. The modulation and/or pulse shape to be applied and the amplitude of the microwave energy are determined by the required properties of the concrete dried material. Thus, films which are largely free of cavities require low microwave power and/or short microwave pulses and long pauses. The pulse duration of the microwave irradiation is to be 10 to 95% of the period duration of the power profile according to the present invention.

In applications in which the drying of thin layers is necessary, the use of applicators which represent single-mode or multimode resonators is advantageous.

Furthermore, the use of multiple different coupled resonators is advantageous to allow the required microwave power to work at the appropriate location and/or at the appropriate time on the material corresponding to the changing dielectric properties of the material to be dried. If a microwave tunnel having multiple feeds is used, the coupling of the different feed points is set up in accordance with the degree of drying and the required drying speed.

If single-mode or multimode resonators having known mode shape are used, the required modulation of the microwave irradiation may be performed by adapting the length of the resonator and the transport velocity as the material to be dried is transported through the resonators.

The low-contaminant hydrocolloids and/or hydrogels which are dried uniformly and carefully while largely maintaining the starting molar mass under the effect of the thermal energy of microwaves, having a density of 0.05 to 1.50 g/1 cm³ and a residual water content of 1 to 80 mass-%, possibly in the form of planar formations, on the basis of natural, biotechnologically produced, and/or semisynthetic polysaccharides and possibly 0.01 to 60 mass-%, in relation to the hydrocolloids and/or hydrogels, of additives, are particularly suitable as cosmetics, for topical ophthalmological, dermal, and/or transdermal application of active ingredients, in particular as a "drug delivery system," as components for implants, as components for treating injuries caused by arteriosclerosis, arthritis, thromboses, and/or traumatic injuries, for encouraging angiogenesis, wound healing, and anti-inflammatory processes as well as a support matrix for use in cell culture technology.

The use is preferably in the form of coated and/or impregnated carrier materials, in particular woven fabrics, scrims, nonwoven fabrics, knitted fabrics, or cushion-like materials and in the form of gels, membranes, films, microspheres, salves, and/or foams.

A further application of the low-contaminant hydrocolloids and/or hydrogels which are dried uniformly and carefully while largely maintaining the starter molar mass under the effect of the thermal energy of microwaves, having a residual water content of 1 to 80 mass-%, is the improvement of the sliding ability of medications, products, and devices made of glass, ceramics, plastics, and/or natural materials, in particular prosthetic products, catheters, ultrasound measuring heads, and endoscopy instruments. Increasing the sliding capability results from the water absorption of the colloids in the coating when liquid is supplied. The increased sliding capability causes a reduction of irritation of the epidermis in medical use and makes the insertion of catheters into bodily openings easier in particular.

In coated medications, the hydrocolloids or hydrogels used act simultaneously as a "drug delivery system."

The present invention is explained by the following examples:

Example 1

Housing of ultrasound measuring heads having a surface area of approximately 85 cm² made of polypropylene runs continuously through an immersion station, which contains a coating formula made of 22 g hyaluronic acid, 12 g carboxy methyl cellulose, 4 g glycerin, and 0.3 g sorbic acid dissolved in 1 l water, and is subsequently guided at a passage velocity of 0.17 m/minute through a 2.5 m long microwave tunnel having four feed points adapted differently to the degree of drying of the material of a total power consumption of approximately 8.5 kW, through which the air from the heat exchangers of the microwave generators, which is heated to 40 to 45°C, is guided simultaneously. The resulting abrasion-resistant coating of the measuring head housing has a thickness of 250 µm, a water content of 12 mass-%, and does not display any discoloration as a result of the heat treatment.

Example 2

To produce shoe insert material against sweaty feet, an aqueous, high-viscosity solution, which contains 2 wt.-% carboxy methyl cellulose, 5 mass-% alginic acid, 10 mass-% guar gum, 2 mass-% sodium hyaluronate, 0.05 mass-% aluminum stearate, 0.01 mass-% Isodorant®, and 1 mM phosphate buffer, is squeegeed in the form of an 8 mm thick layer onto a 3.5 mm thick cotton fabric, which is impregnated with a 0.05 M calcium chloride solution, and dried at a passage velocity of 0.25 m/minute in the microwave tunnel according to example 1. The residual water content of the coated cotton fabric is 5.5 mass-%.

Example 3

A 5% solution of hyaluronic acid benzyl ester (molar mass weight mean by GPC analysis 2.8 x 10^6) is applied to the Teflon-coated transport belt of the microwave tunnel according to example 1 and peeled off after passing through the microwave tunnel at 0.08 m/minute as a 750-µm film having a residual water content of 8.5%.

The GPC analysis of the peeled film results in a molar mass weight mean of the dried hyaluronic acid benzyl ester of 2.4 x 10^6.

Example 4

0.5 ml/cm² of a sodium hyaluronate solution is poured onto the inner base of cell culture bottles made of polyethylene (diameter 75 mm) and uniformly distributed by a shaking apparatus. The cell culture bottles pass through the microwave tunnel according to example 1 at 0.55 m/minute and subsequently pass through a sterilization and packaging station. The analysis of the sodium hyaluronate coating dried by the microwave effect in the cell culture bottles results in a water content of 16.5 mass-%. The bottles are used for cultivating cell cultures, in particular for cultivating keratinocytes.

Patent Claims

1. Dried low-contaminant hydrocolloids and/or hydrogels having a density of 0.05 to 1.50 g/cm³ and a residual water content of 1 to 80 mass-%, possibly in the form of planar formations, based on unmodified and/or modified natural, biotechnologically produced, and/or semisynthetic polysaccharides and possibly 0.01 to 60 mass-%, in relation to the hydrocolloids and/or hydrogels, of additives, **characterized in that** the drying of the hydrocolloids and/or hydrogels occurs uniformly and carefully while largely maintaining the starting molar mass under the effect of the thermal energy of microwaves and possibly the thermal energy of heated gases and/or IR radiators.

2. The dried low-contaminant hydrocolloids and/or hydrogels according to Claim 1, characterized in that the unmodified and/or modified natural, biotechnologically produced, and/or semisynthetic polysaccharides are pectins, chitins, chondroitins, heparins, starches, dextrans, pullulans, xanthans, welans, rhamsans, curdlans, alginates, carrageenans, keratans, hyaluron acids, dermatans, gellans, schizophyllans, and/or polysaccharides made of carob flour, agar, gum Arabic, tragacanth gum, guar gum, fenugreek gum, locust bean gum, and/or tara gum.

3. The dried hydrocolloids and/or hydrogels according to Claims 1 and 2, characterized in that the additives are 0.1 mass-% to 25 mass-% film-forming binders and/or thickeners based on plastics and/or semisynthetic modified natural materials, in particular cellulose derivatives, 0.01 mass-% to 0.25 mass-% preservatives, in particular p-hydroxy benzoic acid ester and/or sorbic acid, 1 mass-% to 30 mass-% stability-improving fibrous carrier materials and/or stability-improving carrier materials in the form of textiles and/or latticed planar formations, 0.05 to 10 mass-% mineral materials, 0.05 to 3 mass-% micelle-forming materials, in particular nonionic emulsifiers, 1 to 25 mass-% softeners, in particular glycerin, 0.05 to 30 mass-% cosmetic and/or pharmaceutical active ingredients, in particular vitamins and/or agents which encourage skin penetration, 1 to 30 mass-% vehicles for active ingredients, in particular liposomes, 0.05 to 2 mass-% antioxidants, in particular ascorbic acid, 0.05 to 2% odorants, in particular ethereal oils, and/or 0.05 to 5 mass-% colorants, each in relation to the hydrocolloids and/or hydrogels.

4. The dried hydrocolloids and/or hydrogels according to Claims 1 through 3, characterized in that the stability-improving fibrous carrier materials and/or stability-improving carrier materials in the form of textiles and/or latticed planar formations comprise cellulose, cellulose esters, calcium alginate, wool, cotton, silk, polyamides, polyesters, polyethers, polyvinyl alcohol, and/or polyolefins.

5. The dried hydrocolloids according to Claims 1 through 4, characterized in that the dried hydrocolloids have a molar mass numeric mean of at least 75% of the molar mass numeric mean of the hydrocolloids used as the starting product.

6. A method for producing low-contaminant hydrocolloids and/or hydrogels which are dried uniformly and carefully while largely maintaining the starting molar mass, having a residual water content of 1 to 80 mass-% and a density of 0.05 to 1.50 g/cm³, possibly in the form of planar formations, on the basis of unmodified and/or modified natural, biotechnologically produced, and/or semisynthetic polysaccharides and possibly 0.1 to 60 mass-%, in relation to the hydrocolloids and/or hydrogels, of additives according to one more of Claims 1 through 5 and possibly 0.1 to 10 mass-%, in relation to the hydrocolloids or hydrogels, of propellants, characterized in that the drying is performed under the effect of the thermal energy of microwaves and possibly the thermal energy of heated gases and/or IR radiators.

7. The method for producing low-contaminant hydrocolloids and/or hydrogels which are dried uniformly and carefully while largely maintaining the starting molar mass according to Claim 6,

characterized in that the effect of the thermal energy of the microwaves occurs simultaneously and/or after the effect of the thermal energy of heated gases and/or IR radiators and the ratio of microwave energy to temperature and to the throughput quantity of the gas is set in such a way that the proportion of the microwave energy to the total energy applied for drying the hydrocolloids is 95 to 10% and the gases used for drying the hydrocolloids are preferably entirely or partially heated in the heat exchanger of the microwave generators, the frequency of the microwaves preferably being 2.4 to 2.5GHz.

8. The method for producing low-contaminant hydrocolloids and/or hydrogels which are dried uniformly and carefully while largely maintaining the starting molar mass according to Claims 6 and 7, characterized in that the effect of the thermal energy of the microwaves is introduced at a frequency preferably from 2.4 to 2.5GHz as continuous power or as modulated and/or pulsed power, the modulation being entirely or partially implemented by the transport of the hydrocolloids through single-node or multimode resonators having one or more of microwave feed points and the pulse duration of the microwave irradiation being 10 to 95% of the period duration of the power profile.

9. A use of low-contaminant hydrocolloids and/or hydrogels which are dried uniformly and carefully while largely maintaining the starting molar mass, having a density of 0.05 to 1.50 g/cm³ and a residual water content of 1 to 80 mass-%, possibly in the form of planar formations, based on unmodified and/or modified natural, biotechnologically produced, and/or semisynthetic polysaccharides and possibly 0.01 to 60 mass-%, in relation to the hydrocolloids and/or hydrogels, of additives, according to one more of Claims 1 through 8 as cosmetics, for topical ophthalmological, dermal, and/or transdermal application of active ingredients, in particular as a "drug delivery system," as components for implants, as components for treating injuries caused by arteriosclerosis, arthritis, thromboses, and/or traumatic injuries, for encouraging angiogenesis, wound healing, and anti-inflammatory processes and as a support matrix for use in cell culture technology, the use preferably being in the form of coated and/or impregnated carrier materials, in particular woven fabrics, scrims, nonwoven fabrics, knitted fabrics, or cushion-like materials and in the form of gels, membranes, films, microspheres, salves, and/or foams.

10. A use of low-contaminant hydrocolloids and/or hydrogels which are dried uniformly and carefully while largely maintaining the starting molar mass, having a residual water content of 1 to 80 mass-%, possibly in the form of planar formations, based on unmodified and/or modified natural, biotechnologically produced, and/or semisynthetic polysaccharides and possibly 0.01 to 60 mass-%, in relation to the hydrocolloids and/or hydrogels, of additives, according to one more of Claims 1 through 8 to improve the sliding capability of medications, products and devices made of glass, ceramic, plastics, and/or natural materials, in particular prosthetic products, catheters, ultrasound measuring heads, and endoscopy instruments.